

Attorney Docket No.: PENN0870US.NP  
Inventors: Sweeney et al.  
Serial No.: 10/566,796  
Filing Date: April 2, 2008  
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#### REMARKS

Claims 1-18 are pending in the instant application. Claims 1-18 have been rejected. Claims 1, 5, 10 and 14 have been amended. Support for these amendments is provided in the specification at, for example, page 5, lines 28-33, page 6, lines 31-33 and page 13, lines 23-29. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Finality of Species Election Requirement**

The Examiner made final the species election requirement mailed March 10, 2010. Applicants respectfully disagree that art cited by the Examiner is relevant to the instant claimed invention. Detailed arguments are provided in Section V herein. As Applicants believe the generic claim is in condition for allowance, consideration of claims to additional species which depend from or otherwise require all the limitations of the allowable generic claim is requested.

#### **II. Rejection of Claims 1-18 under 35 U.S.C. 112, first paragraph**

##### **- Written Description**

Claims 1-18 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that the specification does not provide adequate written description for the

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phrase "derivative thereof".

Applicants respectfully traverse this rejection.

MPEP 2163 states "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention."

The phrase "BBI or derivative thereof" is specifically defined at page 13 of the instant application to include any Bowman Birk Inhibitor or Bowman Birk Inhibitor product, including, but not limited to, BBI prepared by methods known in the art, BBI concentrates prepared in accordance with methods known in the art including, but not limited to those taught in U.S. Patent 5,217,717 (which is incorporated herein by reference in its entirety), and any synthetically derived compounds which mimic the biological activities, and in particular the serine protease inhibitory activity, of BBI.

Applicants believe this definition in the specification provides a description of sufficient particularity such that one skilled in the art would recognize that Applicants had possession of the claimed invention. Thus, Applicants believe the instant application meets the written description requirements with respect to the phrase "or derivative thereof".

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However, in an earnest effort to advance the prosecution of this case, the phrase "or derivative thereof" has been replaced in the pending claims with the more particular recitation of a synthetically derived compound which mimics protease inhibitory activity of Bowman-Birk Inhibitor. Support for this amendment is provided by the written description at pages 5 and 13 of the instant application.

Withdrawal of this rejection is therefore respectfully requested.

**III. Rejection of Claims 1-4 and 10-13 under 35 U.S.C. 112, first paragraph- Enablement**

Claims 1-4 and 10-13 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner has acknowledged the specification to be enabling for treating skeletal muscle atrophy in a subject comprising administering a Bowman-Birk inhibitor concentrate. However, the Examiner suggests that the specification does not reasonably provide enablement for preventing skeletal muscle atrophy in a subject.

Accordingly, in an earnest effort to advance the prosecution, Applicants have amended claim 10 to delete the phrase "or preventing". Further Applicants have amended claim 1 by replacing the term "preventing" with the phrase "inhibiting progression of" in accordance with teachings beginning at page 6, line 31 of the

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instant specification.

Withdrawal of this rejection is therefore respectfully requested.

**IV. Rejection of Claims 1-18 under 35 U.S.C. 112, second paragraph**

Claims 1-18 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the phrase "or derivative thereof" is vague and indefinite.

Accordingly, in an earnest effort to advance the prosecution of this case, the phrase "or derivative thereof" has been replaced in the pending claims with the more definitive recitation of a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk Inhibitor. Support for this amendment is provided at pages 5 and 13 of the instant application.

Withdrawal of this rejection is therefore respectfully requested.

**V. Rejection of Claims 1-18 under 35 U.S.C. 102(b) or 103(a)**

Claims 1-18 have been rejected under 35 U.S.C. 102(b) as being anticipated by Baxter et al. (U.S. Patent 2,596,090).

Claims 1-18 have also been rejected under 35 U.S.C. 102(b) as being anticipated by Hove et al. as evidenced by Baxter et al. (U.S. Patent 2,596,090).

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Claims 1-18 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Baxter et al. (U.S Patent 2,596,090).

Claims 1-18 have also been rejected under 35 U.S.C. 103(a) as being anticipated by Hove et al. as evidenced by Baxter et al. (U.S. Patent 2,596,090).

Applicants respectfully traverse these rejections.

The Examiner suggests that these references teach vitamin E (tocopherol) can be extracted from soybean oil and is useful in muscular dystrophy. The Examiner further suggests that vitamin E is a soybean extract and that Applicant's define Bowman-Birk inhibitor concentrate as a soybean extract at page 6 of the patent application.

The focus of Hove is a study to determine the effect on the high urinary secretion of creatine associated with muscular dystrophy when  $\alpha$ -tocopherol is administered and whether the effect was due to the level of highly unsaturated fat acids in the oil (see Hove, page 95, end of 2<sup>nd</sup> full paragraph).

The teaching of Baxter in 2,596,090 relates to a method for improving the vitamin E biological activity of certain non- $\alpha$ -tocopherol compounds and, in 2,891,864, to a composition of vitamin E active material prepared from vegetable oil deodorizer sludge for use in fortifying animal feed.

It is respectfully pointed out that tocopherols with vitamin E

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activity and Bowman-Birk inhibitor are completely different compounds with completely different chemical structures and activities. Tocopherols are a class of chemical compounds having a chromanol ring (chroman ring with an alcoholic hydroxyl group) and a saturated 12-carbon aliphatic side chain containing two methyl groups in the middle and two more methyl groups at the end. They act as antioxidants protecting cells against damage from free radicals. In contrast, the National Cancer Institute Drug Dictionary at <http://www.cancer.gov/drugdictionary/?CdrID=433272> defines Bowman-Birk inhibitor concentrate as an extract of soybeans enriched in Bowman-Birk inhibitor (BBI), a soybean-derived, 71 amino acid polypeptide and serine protease inhibitor containing distinct inhibitory sites for trypsin and chymotrypsin. The instant specification at page 5 also teaches that BBI is a well-characterized dietary protease inhibitor, with a molecular weight of approximately 8000 Da and the ability to inhibit the activity of numerous proteases, such as chymotrypsin, trypsin, cathepsin G, elastase, and chymase.

In no way do the teachings of Baxter and Hove, which relate to the completely different compound of tocopherol with a completely different chemical structure and activity, anticipate or render obvious the instant claimed invention involving administering to the subject a composition comprising Bowman-Birk inhibitor or a

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synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk inhibitor.

These references, which are completely unrelated to Bowman-Birk inhibitor or the protease inhibitory activity associated with the use of a Bowman-Birk inhibitor, clearly lack the teaching of all claim elements as required by MPEP 2131 to anticipate the instant claimed invention under 35 U.S.C. 102(b). Further, these references which relate to completely different compounds with completely different chemical structures and activities to Bowman-Birk inhibitor clearly lack the required teaching or suggestion of all claim limitations and any reasonable expectation of success with respect to the instant claimed invention involving administering to the subject a composition comprising Bowman-Birk inhibitor or a synthetically derived compound which mimics the protease inhibitory activity associated with the use of Bowman-Birk inhibitor. Thus, in no way do these references establish a prima facie case of obviousness with respect to the instant claimed invention under 35 U.S.C. 103(a). See MPEP 2143.

Withdrawal of all rejections under 35 U.S.C. 102(b) and 103(a) is therefore respectfully requested.

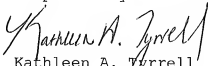
## **VI. Conclusion**

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kathleen A. Tyrrell". The signature is fluid and cursive, with the first name "Kathleen" and last name "Tyrrell" clearly distinguishable.

Kathleen A. Tyrrell  
Registration No. 38,350

Date: August 17, 2010

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, NJ 08053  
ktyrrell@licataandtyrrell.com  
856-810-1515